Rheumatism * * * This preparation combines the best known chemicals for the treatment of Arthritis and Rheumatism. It aids in building up blood cells, improving the quality of the blood, absorbing inflammatory matter, increasing stomach functions, stimulating intestinal muscles, aiding digestion, improving the appetite and reducing the need for sedatives * * *." The tablets were misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 18, 1951. Default decree of condemnation and destruction.

3566. Misbranding of Dr. Means' Pills. U. S. v. 20 Dozen Boxes * * *. (F. D. C. No. 29091. Sample No. 13717–K.)

LIBEL FILED: May 1, 1950, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 1, 1949, from Buffalo, N. Y.

PRODUCT: 20 dozen boxes, each containing 30 pills, of *Dr. Means' Pills* at Lebanon, Pa., in possession of the Dr. W. B. Means Co. The pills were repackaged into boxes by the consignee from a bulk shipment.

LABEL, IN PART: "Dr. Means' Pills Each pill contains Strychnine Sulphate 1/200 gr., Acetanilid 1½ gr., with Caffeine Alkaloid and Camphor."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users since the article contained acetanilid and strychnine, and its labeling failed to warn that frequent or continued use may be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug; that not more than the dose recommended should be taken; that the article should not be given to children; and that its use by elderly persons may be dangerous. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 18, 1951. The Dr. W. B. Means Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3567. Misbranding of Halox Therapeutic Generator. U. S. v. 22 Devices * * *. Tried to the court. Decree of condemnation. (F. D. C. No. 24848. Sample No. 31725–K.)

LIBEL FILED: May 20, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about April 30, May 9 and 14, July 24, and December 3, 1947, by the Halox Therapeutic Generator Co., from Central, N. Mex.

PRODUCT: 22 devices known as *Halox Therapeutic Generator* at Los Angeles, Calif. Examination showed that the device was designed to produce chlorine gas by means of electrolysis.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the conditions for which it was intended, and it failed also to bear adequate directions for use by reason of its failure to state all of the disease conditions for which the article was intended, namely, arthritis, sinusitis, hay fever, bronchitis, neuritis, sciatica, rheumatism, asthma, and nervous disorders.

DISPOSITION: Albert P. Mracek, trading as the Halox Therapeutic Generator Co., claimant, having filed an answer denying that the devices were misbranded, the case came on for trial before the court on the basis of a stipulated record. After consideration of the evidence and the briefs of counsel, the court, on July 27, 1951, handed down the following opinion:

BYRNE, *District Judge:* "This proceeding in rem was instituted by the United States pursuant to the provisions of the Federal Food, Drug and Cosmetic Act, 52 Statutes 1040, 21 U. S. C. A., section 301 et seq., seeking a decree condemning 22 devices, more or less, labeled in part 'Halox Therapeutic Generator.' The particular authority for this action is to be found in section 334 (a) of 21 U. S. C. A., which provides in part:

> (a) Any article of food, drug, device, or cosmetic that is . . . *misbranded* when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, *or at any time thereafter,* on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . . [Emphasis added.]

"It is the libelant's position that the 22 articles of device (hereinafter referred to as the 'devices' or 'generators') are liable to condemnation in that the generators were misbranded when introduced into, and while in, interstate commerce.

"These generators are devices for the electrolysis of sodium chloride (salt) solution. The device is housed in a leatherette-covered plywood cabinet, its base being approximately 12 inches by 15 inches, and its height approximately 12 inches. At the front of the cabinet is a control panel. Inside the cabinet there is placed a glass jar which is partly filled with a saturated sodium chloride (salt) solution. Carbon electrodes extend into this solution. When the generator is in operation, electricity is carried to these electrodes. As a result of the electrolysis of the salt solution, chlorine gas is produced. A small electric fan blows a current of air through the jar and out through a rubber hose. Thus a mixture of air and chlorine gas goes into the tube. This mixture is then administered to the person receiving the treatment known as 'chlorine inhalation therapy.' This is accomplished by having the patient hold the rubber tube to his nose and inhale the mixture.

"Subsequent to the filing of the libel, a monition issued directing the United States Marshal to seize the generators. In pursuance thereof the generators were seized and notice thereof was published, along with notice to all persons interested in said generators to present their claims to this court.

"One Albert P. Mracek, doing business as Halox Generator Company, appeared and made claim to the generators. Thereafter the claimant filed an answer denying that the generators were misbranded when introduced into, or while in, interstate commerce. The answer also sets up an affirmative defense designed to bring these devices within the administrative exemptions which will be discussed below. There is presently pending in the State of New Mexico an action contesting Mracek's ownership of these generators, but it has been stipulated that, for the purpose of the present action, Mracek shall be deemed to be the proper party claimant.

"21 U. S. C. A. sec. 321 (h) defines a device as follows:

> (h) The term "device" (except when used in paragraph (n) of this section and in sections 331 (i), 343 (f), 352 (c) and 362 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

"21 U. S. C. A. section 352 provides:

> A drug or device shall be deemed to be misbranded . . . (f) unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where

> any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirements.

"Pursuant to the proviso of the above sub-section, the Administrator has promulgated certain regulations which may exempt devices from the requirement that they bear adequate directions for use. The regulation pertinent to this case is to be found in 21 C. F. R., section 1.106 (e) which provides:

> (e) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the act, (21 U. S. C. A. sec. 352 (f) (1)) if it complies with all the conditions set forth in paragraphs (b) (3) and (6) of this section and if such shipment or delivery is made to a physician, dentist, veterinarian, hospital, or clinic to be dispensed by or under the direction of physicians, dentists, or veterinarians in their professional practices.

"Paragraph (b) (3), referred to in the above regulation, requires that information adequate for the use of such device by physicians, dentists, or veterinarians must be readily available.

"The regulations in section 1.106 (k) (2) define a 'physician' as follows:

> The terms "physician," "dentist," and "veterinarian," as used in relation to the exemption of any drug or device, include only those physicians, dentists, and veterinarians who are licensed by law to administer or apply such drug or device.

"From this statement of the pertinent provisions of the Act and Regulations we may now turn to the facts as stipulated to by the parties, to ascertain whether the generators bore adequate directions for use or, if not, whether they were exempt from such requirement by virtue of the above-quoted regulations.

"All twenty-two generators, which have been libelled, were manufactured by the Halox Therapeutic Generator Company, at Central, New Mexico. They were transported from New Mexico to California at various times during the year 1947, and were seized within the County of Los Angeles, California, in May 1948. No written, printed or graphic matter accompanied any of the generators except for the following statements on a metal plate affixed to each generator:

> Patent No. 2256212
> Other patents pending
> Type . . . . No. 704
> Halox Therapeutic Generator Co.
> Scientific Chlorine Inhalators
> Volts 110 Amps. Cyc. 60
> Central, New Mexico, U. S. A.

"All, save one, of these devices were shipped to Dr. W. G. Keys, D. C., who held a valid license as a chiropractic doctor from the State of California. Dr. Keys maintained several offices in Los Angeles County at which these devices were used by him in his practice. The remaining generator was in the possession of another chiropractor, Dr. C. J. Henaghan, D. C. On December 1, 1947, Dr. Keys leased his practice, offices, and equipment to three lessees, one of whom was Dr. Henaghan, and these lessees were in possession of the generators at the time they were seized.

"Prior to December 1947, the Halox Therapeutic Generator Company was owned by Reverend Roger Aull. Father Aull also founded and owned a second organization known as the 'Father Aull Foundation.' The company manufactured the generators and the Foundation promoted the distribution of them. The devices which were shipped to Dr. Keys were *leased* to him under a printed lease agreement bearing the name of the Father Aull Foundation, but which actually designated Reverend Roger Aull as the lessor.

"A bill of sale of the Halox Therapeutic Generator Company, including the devices involved here, was executed by Reverend Roger Aull in favor of the claimant, Mracek, under date of December 1, 1947. This bill of sale was to be effective as of its date, but was not delivered to Mracek until after final shipment of generators to Dr. Keys on December 3, 1947.

"The record contains the following stipulation: 'The parties agree that the devices under seizure were intended for use in the conditions of arthritis, sinusitis, hay fever, and bronchitis.' The libelant also contends that the generators were intended for use in other conditions, namely, neuritis, sciatica, rheumatism, asthma, nervous disorders, ovarian conditions, prostate trouble, and allergies. The claimant denies this contention. The government bases its position on the fact that the Father Aull Foundation, in its lease agreement with Dr. Keys, reserved the power to control all advertising. Samples of the advertising disseminated by the chiropractors using the seized devices are a part of the record. Such advertisements show that the generators were advertised as being appropriate for the treatment of the conditions mentioned above. The failure of the Father Aull Foundation to object to such advertising, which it had reserved the power to control, is convincing evidence that the generators were intended for use in such conditions.

"At the outset it is clear that the generators did not bear adequate directions for use. In fact they bore no directions for use. This much is admitted by the claimant who rests his case on the proposition that the devices were exempt from this requirement by virtue of the exemption regulations set out above. It is the claimant's position that the devices were shipped or delivered to physicians to be dispensed by physicians in their professional practice. It is at once apparent that the claimant can succeed only if a chiropractor is a 'physician' within the meaning of the regulations.

"As was pointed out earlier, the regulation provides that the term 'physician' includes only those physicians who are licensed by law to administer or apply the drug or device in question. Thus, the persons to whom the devices were shipped must, first of all, be physicians. Only if they be physicians is it necessary to inquire into the matter of their authority to administer or apply the device.

"In its broadest sense the term 'physician' includes anyone exerting a remedial or salutary influence; as a physician of the soul. However, I do not believe the term as used in the regulation was intended in the broad sense. In Webster's New International Dictionary (unabridged), 2nd ed., 1949, one definition of 'physician' is: 'A person skilled in physic or the art of healing.' In the same volume 'chiropractic' is defined as: 'A system for the practice of adjusting the joints, especially at the spine, by hand, for the curing of disease.' Thus a chiropractor is one skilled in the art of healing, in a limited manner, although not one skilled in physic, since this latter term refers to the practice of medicine. In Webster's Dictionary, supra, a second definition of 'physician' is: 'one duly authorized to treat diseases especially by medicines; *a doctor of medicine*; often distinguished from a surgeon.' [Emphasis added.] Section 15 of the Chiropractic Law of the State of California, Deering's General Laws, 1944 ed., Act 4811; provides in part: '. . . any licensee under this act who uses . . . *the term "physician,"* . . . or any other letters, prefixes or suffixes, the use of which would indicate that he or she was practicing a profession for which he held no license from the state of California, . . . shall be guilty of a misdemeanor . . .' [Emphasis added.] It follows that one who is licensed to practice chiropractic in the state of California is not a physician by virtue of such license. The record is devoid of any evidence attributing qualifications as physicians to the chiropractors concerned here.

"There is, in addition, a more compelling reason for holding that the seized generators were not exempt from the requirement that they bear adequate directions for use. The exemption regulations define a physician as a physician who is licensed by law to administer or apply the drug or device in question. Thus, even if the term 'physician' is broad enough to include chiropractors, it includes only those chiropractors who are licensed by law to administer or apply the drug or device.

"The authority of a licensed chiropractor is defined by section 7 of the Chiropractic Law, supra, which provides:

> sec. 7. Certificate to practice. One form of certificate shall be issued by the board of chiropractic examiners, which said certificate shall be designated "License to practice chiropractic," which license shall authorize the holder thereof to practice chiropractic in the state of California as taught in chiropractic schools or colleges; and, also, to use all necessary mechani-

> cal, and hygienic and sanitary measures incident to the care of the body, but shall not authorize the practice of medicine, surgery, osteopathy, dentistry or optometry, nor the use of any drug or medicine now or hereafter included in materia medica.

"The scope of this authority has not been defined by the Supreme Court of California, but other appellate courts of the state have had occasion to consider the question. In *People* v. *Fowler*, 32 Cal. App. Supp. 737, 84 P. 2d 326, the court first considered the meaning of the authorization 'to practice chiropractic . . . as taught in chiropractic schools or colleges.' The court held that this section authorized licensees to practice chiropractic as taught in chiropractic schools or colleges *at the time of the enactment of the Chiropractic Law.* The court observed that the term 'chiropractic' had a well-established and quite definite meaning when the statute was enacted, that is, that chiropractic is a system for the practice of adjusting the joints, especially at the spine, by hand, for the curing of disease. The court further held that the words 'as taught in chiropractic schools or colleges' did not set at large the meaning of 'chiropractic' and thereby leave the schools and colleges free to enlarge its meaning by changes in their curriculum. It at once is obvious that chlorine gas inhalation therapy administered by a machine does not fall within the meaning of 'chiropractic' as set out above, since it in no way involves the manipulation of joints by hand or otherwise. Furthermore the record contains the affidavits of two licensed chiropractors who are presently engaged in the training of students at the Los Angeles College of Chiropractic. One affiant is the Dean of the College and the other is the Director of the College Clinic. Both state that they do not know of any school of chiropractic that teaches or has taught chlorine gas inhalation therapy.

"However, section 7 of the Chiropractic Law contains a further authorization, namely, 'to use all necessary mechanical, and hygienic and sanitary measures incident to the care of the body.' In People v. Fowler, supra, the court held that this phrase 'is not a definition of, but an addition to, chiropractic as used in the previous part of section 7 and authorizes chiropractors to use measures which would not otherwise be within the scope of their licenses.'

"*In Re Hartman*, 10 Cal. App. 2d 213, 51 P. 2d 1104, the court, in referring to this clause stated:

> . . . that clause of the section refers to general hygienic and sanitary measures, even though mechanical, *and not to the treatment of diseases and ailments.* [Emphasis added.]

"Thus it is clear that a chiropractor licensed by the State of California is not authorized to treat diseases and ailments by mechanical means. As we have seen, the parties are agreed that the generators under seizure were intended for use in the conditions of arthritis, sinusitis, hay fever, and bronchitis. Furthermore, I find that the devices were intended for use in other conditions. All these conditions, admitted or disputed, are diseases and as such could not be treated by chiropractors by means of the Halox Therapeutic Generator. It follows that the seized generators were not exempted by the regulations since they were not shipped to physicians who were licensed by law to administer them.

"There is yet a third reason why the seized devices were not exempted by the administrative regulations. Those regulations require that information adequate for the use of such device by physicians be readily available. The record includes the results of an experiment conducted by Mr. Louis C. Weiss, a chemist employed by the Food and Drug Administration. The purpose of the experiment was to determine the chlorine concentration of the output of one of the seized devices at various dial settings. The generator was operated at each such varied dial setting for approximately three hours and the chlorine output was measured six times during each three hour test. In all, some eleven different tests were conducted, each at a different setting. It was Mr. Weiss' conclusion that it 'was impossible to set the dials and provide for a constant output of chlorine'. He stated further, 'For instance, during a typical run, the chlorine output varied in a two-hour period from 407.0 to 12.2 parts per million, a variation of 3300%, although the dial settings were unchanged.'

"The record also includes the affidavit of Dr. Clinton Hobart Thienes, M. D., chairman of the Department of Pharmacology at the University of Southern California Medical School. Dr. Thienes states that the use of chlorine gas in an effective antiseptic concentration would be too irritating to be withstood by the average individual and that concentrations less than this are ineffective for any purpose. He states further that chlorine gas to be safely inhaled for even a short time requires a concentration of less than ten parts per million. The results of Mr. Weiss' test show that a constant output of such a safe amount was obtained at only two dial settings. Yet nowhere in the record is it shown that directions were available suggesting such dial settings. Furthermore, at these settings the chlorine output varied throughout the three hour period. Thus it is clear that adequate directions were not available for the use of the generators.

"Dr. Thienes stated that on the basis of the Weiss affidavit he was of the opinion that it would be extremely difficult to regulate the output of the Halox Therapeutic Generator to consistently elicit a safe output of chlorine. He further stated: 'I would consider the Halox Therapeutic Generator as being incapable of effective operation in the treatment of any disorder *and would consider that it would be impossible to devise for it any adequate directions for use.*'

"It is not necessary to determine whether adequate directions could be devised, although that possibility may be doubted. It is certain, however, that adequate directions were not available to the persons to whom the seized generators were shipped.

"The twenty-two devices, more or less, labeled in part 'Halox Therapeutic Generator' must be condemned and disposed of by destruction in accordance with the provisions of 21 U. S. C. A., Sec. 334 (d). Libelant shall recover its costs.

"Libelant is requested to prepare findings of fact and conclusions of law in conformity with this opinion."

In accordance with the foregoing opinion, findings of fact and conclusions of law were handed down. On September 11, 1951, judgment of condemnation was entered, and the court ordered that 3 of the devices be delivered to the Food and Drug Administration and that the remainder of the devices be destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3568. Adulteration of Fleaseed husks (Plantago). U. S. v. 12 Bags * * *. (F. D. C. No. 30931. Sample No. 23904–L.)

LIBEL FILED: April 17, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about October 23, 1950, from India.

PRODUCT: 12 92-pound bags of *fleaseed husks* at Brooklyn, N. Y. Fleaseed is another name for the drug, Plantago.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 21, 1951. Default decree of condemnation and destruction.

3569. Adulteration of psyllium seed husks. U. S. v. 67 Bags * * *. (F. D. C. No. 30933. Sample No. 23917–L.)

LIBEL FILED: April 19, 1951, Eastern District of New York.

ALLEGED SHIPMENT: From India, arriving on or about November 21, 1950.

PRODUCT: 67 92-pound bags of *psyllium seed husks* at Brooklyn, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The